



7-3096

Applicant:

Roy Curtiss and Steven A. Tinge

Serial No.:

08/473,789

Group Art Unit: 1802

Filed:

June 7, 1995

Examiner: P. Murthy

For:

Recombinant Bacterial Vaccine System With Environmentally Limited Viability

Assistant Commissioner for Patents Washington, D.C. 20231

## RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Action mailed May 14, 1996, applicants provisionally elect for prosecution Group II, claims 20-26 and 30-35, with traverse. Also submitted is a Petition for Extension of Time for one month to extend the period for response to and including July 13, 1996, and the appropriate fee for a small entity.

In the Office Action mailed May 14, 1995, the claims were divided into 2 groups, Group I, claims 1-19 and 27-29, drawn to recombinant microbial cells and a method of making such cells; and Group II, claims 20-26 and 30-35, drawn to recombinant microbial cells expressing a desired expression product, such cells for use as a vaccine, and a method of using such cells to induce immunoprotection in an animal. Applicants first note that the Office Action indicates that claims 20-26 and 30-35 are drawn to vectors and their use. In

fact, the claims are drawn to microbial cells (which may contain vectors) and their use. It does not appear that this misidentification materially affects the requirement for restriction.

Applicants traverse the restriction requirement as currently set forth for the following reasons. Applicants first note that sufficient evidence and reasoning for the division of the claims to the cells and the claims to the method of using the cells is not set forth. The present application contains claims to a product (i.e. cells with environmentally limited viability, claims 1-26), a process that is specially adapted for making the product (claims 27-29), and a process of using the product (i.e. a method of inducing immunoprotection in an animal by administering cells with environmentally limited viability). Accordingly, 37 C.F.R. § 1.141 applies. 37 C.F.R. § 1.141 states that:

Where claims to all three categories, product, process of making, and process of use, are included in an application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and process of making the product even though a showing of distinctness between the product and process of using the product can be made.

In this regard, applicants initially note that claims to the cells (claims 1-19) and to the method of making the cells (claims 27-29) are joined together in Group I. This grouping is supported by MPEP § 806.05(f) which indicates that a process of making and a product are distinct only if it can be shown (1) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products, or (2) that the product as claimed can be made by another materially different

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process. Neither of these possibilities are true of the claimed product and process. Since the claims to the product and process of making were not divided, and since such a division would not be proper, the requirements of 37 C.F.R. § 1.141 applies. Accordingly, applicants respectfully request that claims to the cells, method of making the cells and method of using the cells be rejoined in a single group for examination.

Favorable consideration of claims 1-35 is earnestly solicited.

Respectfully submitted,

Patrea L. Pabst

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Date: July 15, 1996

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## Certificate of Mailing under 37 CFR § 1.8(a)

I hereby certify that this Response to Restriction Requirement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Tracy Cogporn

Date: July 15, 1996